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10 (continued on next page)

11 **IN THE UNITED STATES DISTRICT COURT
12 FOR THE NORTHERN DISTRICT OF CALIFORNIA**

13 THE STATE OF CALIFORNIA; THE STATE OF
14 CONNECTICUT; THE STATE OF DELAWARE;
15 THE DISTRICT OF COLUMBIA; THE STATE OF
16 HAWAII; THE STATE OF ILLINOIS; THE
17 STATE OF MARYLAND; THE STATE OF
18 MINNESOTA, by and through its Department of
19 Human Services; THE STATE OF NEW YORK;
20 THE STATE OF NORTH CAROLINA; THE
21 STATE OF RHODE ISLAND; THE STATE OF
22 VERMONT; THE COMMONWEALTH OF
23 VIRGINIA; THE STATE OF WASHINGTON,
Plaintiffs,

THE STATE OF OREGON,
Intervenor-Plaintiff,

v.

ALEX M. AZAR, II, in his Official Capacity as
Secretary of the U.S. Department of Health &
Human Services; U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES; R.
ALEXANDER ACOSTA, in his Official Capacity
as Secretary of the U.S. Department of Labor; U.S.
DEPARTMENT OF LABOR; STEVEN
MNUCHIN, in his Official Capacity as Secretary of
the U.S. Department of the Treasury; U.S.
DEPARTMENT OF THE TREASURY;

Defendants,

and,

THE LITTLE SISTERS OF THE POOR, JEANNE
JUGAN RESIDENCE; MARCH FOR LIFE
EDUCATION AND DEFENSE FUND,
Defendant-Intervenors.

Case No. 4:17-cv-05783-HSG

**LITTLE SISTERS' MOTION TO
DISMISS OR IN THE ALTERNATIVE
FOR SUMMARY JUDGMENT;
OPPOSITION TO STATES MOTION
FOR SUMMARY JUDGMENT**

Date: September 5, 2019

Time: 2:00 p.m.

Dept. 2, 4th Floor

Judge: Hon. Haywood S. Gilliam, Jr.

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11 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

12 **PLEASE TAKE NOTICE** that on September 5, 2019, at 2:00 p.m., in Courtroom 2 of the above-
13 titled Court, at 1301 Clay Street, Oakland, California, Defendant-Intervenor the Little Sisters of the
14 Poor Jeanne Jugan Residence (Little Sisters) will and hereby do present this motion and opposition.

15 The Little Sisters move this Court to dismiss the Second Amended Complaint and Oregon's
16 Complaint in Intervention, or in the alternative, to enter summary judgment in favor of Defendants
17 and deny the Plaintiff States' motion for summary judgment.

18 This motion is based on this notice, the memorandum of points and authorities, the administrative
19 record, this Court's file, and any matters properly before the Court.

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4	HRSA, <i>Women's Preventive Services Guidelines</i> , U.S. Dep't of Health & Human Servs. (Oct. 2017)	17
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INTRODUCTION

The States can't escape RFRA. If the prior version of the contraceptive mandate violates RFRA, then the agencies of course had authority to comply with federal law and issue the Final Rule to eliminate that illegal burden. And if the prior version of the mandate violates RFRA, then of course this Court cannot lawfully impose the remedy the States openly seek, a reimposition of the prior illegal system.

The States' problem—made unavoidably clear by their summary judgment motion—is that they simply have no plausible RFRA argument. Indeed, after over 18 months of litigation, two preliminary injunctions, and four rounds of briefing in this Court and on appeal, the States can still only muster discredited and abandoned arguments from 2015 and hope that the Court won't look at them all that closely.

Unable to mount a substantive RFRA defense of the prior version of the mandate, the States instead argue against various straw-men versions of the statute. But neither the agencies nor the Little Sisters contend that the mere say-so of a religious objector makes a burden substantial under RFRA, Mot. 22, or that “a substantial burden is present anytime a litigant sincerely believes it,” Mot. 23. Rather, we contend that—as the Supreme Court already found in *Hobby Lobby*—courts should determine the substantiality of a burden by looking at the punishment the government threatens for failure to cease a religious exercise. The States invoke their caricature of Defendants’ RFRA argument to obscure a serious point: they ultimately disagree with the Little Sisters not over whether the threatened fines are substantial, but over whether the Sisters *should* feel religiously obligated not to use the regulatory mechanism for compliance with the Mandate (what the States call the “accommodation”).

Indeed, the States' entire substantial burden analysis is that the so-called accommodation is an "opt-out" from the Mandate that creates a "separate" plan that does not involve the Little Sisters, and

1 to which they should not object. This argument is based on vacated decisions from the courts of appeals
 2 and fails to grapple with what the Supreme Court called “substantial clarification and refinement” of
 3 the government’s position over the course of the *Zubik* litigation. *Zubik v. Burwell*, 136 S. Ct. 1557,
 4 1560 (2016). The government’s concessions that the contraceptive coverage is not actually separate at
 5 all, and that it “could be modified” so it did not use religious objectors’ plans, *id.*, was an admission
 6 that what it was offering religious objectors in the regulatory mechanism was in no way an “opt out.”
 7 More importantly, it was a concession that the regulatory mechanism the States seek to reimpose was
 8 never the least restrictive means—and therefore necessarily fails RFRA.

9 The States know that they need to use religious objectors’ plans for their system to work—that is,
 10 the only way they think they can get coverage to be “seamless” with those plans. Most tellingly, the
 11 States now openly insist that coverage be provided *inside* the religious employer’s plan and not even
 12 one “additional step[] outside of their normal coverage.” Mot. 31. The States even admitted on appeal
 13 that for self-insured plans, the coverage under the accommodation has been part of the “same ERISA
 14 plan” all along.

15 The States’ concessions foreclose any serious argument that contraceptive coverage is “separate”
 16 or “independent” in some way that saves the prior version of the mandate from RFRA. Indeed, now
 17 that it is agreed the coverage is part of the same plan, the substantial burden issue is not even an open
 18 question—rather, it is fully resolved by *Hobby Lobby*’s holding that it is a substantial burden to force
 19 religious employers to provide coverage for religiously-proscribed services. The States’ RFRA
 20 defense of the old rules thus melts away, and with it goes any plausible argument that this Court could
 21 re-impose that illegal system.

22 The States’ other arguments fare no better. They offer no theory under which the agencies lack
 23 authority to issue the Final Rule under the Affordable Care Act or RFRA, but had authority to issue

1 the prior Mandate regulations. The States' argument that the Final Rule is arbitrary and capricious also
 2 ignores the agencies' *Zubik* concessions—the agencies recognized that they could no longer defend
 3 the prior regulations after *Zubik* and explained as much in the Final Rule. The States' Establishment
 4 Clause and Equal Protection arguments fail because, among other reasons, they do not take into
 5 account the government's legitimate interest in protecting the free exercise of religion, and its authority
 6 to do so. Finally, the States' procedural arguments fail because the Final Rule has undergone full notice
 7 and comment.

8 BACKGROUND

9 A. The federal mandate and its exceptions

10 Federal law requires some employers (namely, those with over 50 employees) to offer group
 11 benefits with "minimum essential coverage." 26 U.S.C. § 5000A(f), 26 U.S.C. § 4980H(a), (c)(2).
 12 That "minimum essential coverage" must include, among other things, coverage for "preventive care
 13 and screenings" for women. 42 U.S.C. § 300gg-13(a)(4); 29 U.S.C. § 1185d. Congress did not require
 14 that "preventive care" include contraceptive coverage. Instead, Congress delegated to HHS the
 15 authority to determine what should be included as preventive care "for purposes of this paragraph."
 16 42 U.S.C. § 300gg-13(a)(4).

17 The preventive services mandate was first implemented in an interim final rule on July 19, 2010,
 18 published by the Departments of Health and Human Services, Labor, and Treasury (the agencies). 75
 19 Fed. Reg. 41,726, 41,728 (July 19, 2010) (First IFR). The First IFR stated that the Health Resources
 20 and Services Administration (HRSA), a division of HHS, would produce comprehensive guidelines
 21 for women's preventive services. *Id.* HHS asked for recommendations from the Institute of Medicine
 22 (IOM), 77 Fed. Reg. 8725, 8726 (Feb. 15, 2012), which proposed including, *inter alia*, all FDA-

1 approved contraceptives and sterilization methods.¹ This IFR was enacted without prior notice of
 2 rulemaking or opportunity for prior comment, as it came into effect on the day that comments were
 3 due.

4 Following the comment period on the First IFR, and thirteen days after IOM issued its
 5 recommendations, the agencies promulgated the second IFR. 76 Fed. Reg. 46,621 (Aug. 3, 2011)
 6 (Second IFR). That same day, HRSA issued guidelines on its website adopting the IOM
 7 recommendations in full, mandating all female contraceptive methods. States' Ex. 8 (D4 000284)
 8 HRSA, *Women's Preventive Services Guidelines*, U.S. Dep't of Health & Human Servs. (Aug. 2011)
 9 (2011 Preventive Services Guidelines).

10 The Second IFR stated that it "contain[ed] amendments" to the First IFR. 76 Fed. Reg. at 46,621.
 11 It implemented HRSA's guidelines without notice and comment. *See id.* at 46,623. Not all private
 12 employers are subject to this Mandate. First, the vast majority of employers—namely, those with fewer
 13 than 50 employees—are not required to provide any insurance coverage at all.² Second, approximately
 14 a fifth of large employers are exempt through the ACA's exception for "grandfathered health plans."
 15 *See* 26 U.S.C. § 4980H(c)(2); 42 U.S.C. § 18011; 75 Fed. Reg. 34,538, 34,542 (June 17, 2010); Kaiser
 16 Family Found., *Employer Health Benefits 2018 Annual Survey* 209 (2018), <https://bit.ly/2T4qwbQ>.
 17 For non-exempt employers, the penalty for offering a plan that excludes coverage for even one of the
 18 FDA-approved contraceptive methods is \$100 per day for each affected individual. 26 U.S.C.

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 20 ¹ States' Ex. 18 (D4 000303), Dkt. 313-2 (Institute of Medicine, *Clinical Preventive Services for*
Women: Closing the Gaps, The National Academies Press 10 (2011)).

21 ² According to some estimates, more than 97% of employers have fewer than 50 employees, and
 22 therefore face no federal obligation to provide coverage at all. *See, e.g.*, DMDatabases, *USA Business*
List, <http://bit.ly/10yw56o>. The *Hobby Lobby* Court estimated that "34 million workers" are employed
 23 by firms with fewer than 50 employees. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 700 (2014)
 (citing The White House, Health Reform for Small Businesses: The Affordable Care Act Increases
 Choice and Saving Money for Small Businesses 1).

1 § 4980D(a)-(b). If an employer with more than 50 employees fails to offer a plan at all, the employer
 2 owes \$2,000 per year for each of its full-time employees. 26 U.S.C. § 4980H(a), (c)(1).

3 The Second IFR also granted HRSA “discretion to exempt certain religious employers from the
 4 Guidelines where contraceptive services are concerned.” 76 Fed. Reg. at 46,623. It defined the term
 5 “religious employer” narrowly. *Id.* at 46,626. The Second IFR was effective immediately without prior
 6 notice or opportunity for public comment. The agencies received “over 200,000” comments on the
 7 Second IFR. 77 Fed. Reg. at 8726. Many of the comments explained the need for a broader religious
 8 exemption than that implemented by the Second IFR. However, on February 15, 2012, HHS adopted
 9 a final rule that “finaliz[ed], without change,” the Second IFR. *Id.* at 8725.

10 The agencies then published an Advance Notice of Proposed Rulemaking (ANPRM), 77 Fed. Reg.
 11 16,501 (Mar. 21, 2012), and a Notice of Proposed Rulemaking (NPRM), 78 Fed. Reg. 8456 (Feb. 6,
 12 2013), which were later adopted in a final rule making further changes to the Mandate, 78 Fed. Reg.
 13 39,870 (July 2, 2013). The agencies eventually amended the definition of a religious employer by
 14 eliminating some of the criteria from the Second IFR, limiting the definition to organizations “referred
 15 to in section 6033(a)(3)(A)(i) or (iii) of the [Internal Revenue] Code,” thus exempting “churches, their
 16 integrated auxiliaries, and conventions or associations of churches,” as well as “the exclusively
 17 religious activities of any religious order,” from the Mandate. 78 Fed. Reg. at 39,874; *see* 26 U.S.C.
 18 § 6033(a)(3)(A)(i), (iii). The agencies also adopted a regulatory mechanism for compliance with the
 19 Mandate—termed an “accommodation”—by which religious employers not covered by the exemption
 20 could offer the objected-to contraceptives on their health plans by executing a self-certification and
 21 delivering it to the organization’s insurer or the plan’s third-party administrator (TPA).

22 The system initiated by the first two IFRs did not address the concerns of many religious
 23 organizations, and many filed lawsuits seeking relief. In July 2013, one of those organizations,

1 Wheaton College, received an emergency injunction from the Supreme Court that protected it from
 2 the penalties in the Mandate. *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806 (2014). Following that
 3 injunction, in August 2014, the agencies published a third IFR “in light of the Supreme Court’s interim
 4 order” in *Wheaton*, again without notice and comment. 79 Fed. Reg. 51,092 (Aug. 27, 2014) (Third
 5 IFR). This Third IFR amended the Mandate to allow a religious objector to “notify HHS in writing of
 6 its religious objection” instead of notifying its insurer or third-party administrator. *Id.* at 51,094. The
 7 Third IFR received over 13,000 publicly posted comments. See EBSA, *Coverage of Certain Services*
 8 *Under the Affordable Care Act* (Aug. 27, 2014), <https://www.regulations.gov/document?D=EBSA-2014-0013-0002>. The Third IFR was ultimately finalized on July 14, 2015. 80 Fed. Reg. 41,318 (July
 9 14, 2015). The Third IFR did not accommodate the religious beliefs of the Little Sisters and other
 10 religious objectors, and the Supreme Court revisited the issue in *Zubik v. Burwell*, 136 S. Ct. 1557
 11 (2016) (discussed below).

13 The federal government is also bound—in all of its actions, by any of its parts, under any statute—
 14 to obey federal religious freedom laws. See, e.g., 42 U.S.C. § 2000bb *et seq.* The Religious Freedom
 15 Restoration Act prohibits federal agencies from imposing substantial burdens on religion—they “shall
 16 not” do it—unless the agency demonstrates that the burden is required by a compelling government
 17 interest and there is no “less restrictive” means of achieving that interest. 42 U.S.C. § 2000bb-1; *Hobby*
 18 *Lobby*, 573 U.S. at 728.

19 **B. The challenges to the Mandate and the resulting injunctions**

20 Because the Mandate required that many employers choose between violating their sincere
 21 religious beliefs and paying debilitating fines, dozens of cases were filed against it. Those lawsuits
 22 resulted in dozens of injunctions from federal courts across the country, and multiple such cases were
 23 consolidated at the Supreme Court. See *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (consolidating cases

1 from the Third, Fifth, Tenth, and D.C. Circuits).³ Once the cases reached the Supreme Court, the
 2 agencies made new concessions that changed the facts and arguments they had previously relied on to
 3 defend the Mandate.

4 First, the government admitted for the first time that contraceptive coverage, rather than being
 5 provided as a “separate” plan under the accommodation, must be “part of the same plan as the coverage
 6 provided by the employer,” Br. for the Resp’ts at 38, *Zubik*, 136 S. Ct. 1557 (quotations omitted),
 7 <https://bit.ly/2DiCj32>; Tr. of Oral Arg. at 60-61, *Zubik*, 136 S. Ct. 1557, <https://bit.ly/2VklhFx> (Chief
 8 Justice Roberts: “You want the coverage for contraceptive services to be provided, I think as you . . .
 9 said, seamlessly. You want it to be in one insurance package. . . . Is that a fair understanding of the
 10 case?”; Solicitor General Verrilli: “I think it is one fair understanding of the case.”). The government
 11 thus removed any basis for lower courts’ prior holdings that the Mandate did not impose a substantial
 12 burden on the religious exercise of objecting employers because the provision of contraceptives was
 13 separate from their plans. Cf. Tr. of Oral Arg. at 61, *Zubik*, 136 S. Ct. 1557, <https://bit.ly/2VklhFx>
 14 (Solicitor General Verrilli “would be content” if Court would “assume a substantial burden” and rule
 15 only on the government’s strict scrutiny defense).

16 Next, the agencies admitted to the Supreme Court that women who do not receive contraceptive
 17 coverage from their employer can “ordinarily” get it from “a family member’s employer,” “an
 18 Exchange,” or “another government program.” Br. for the Resp’ts at 65, *Zubik*, 136 S. Ct. 1557,
 19 <https://bit.ly/2DiCj32>. The government also acknowledged that the Mandate “could be modified” to
 20 be more protective of religious liberty, Suppl. Br. for the Resp’ts at 14-15, *Zubik*, 136 S. Ct. 1557,
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23 ³ The various cases challenging the Mandate are collected at Becket, *HHS Mandate Information*
 24 *Central*, <http://www.becketlaw.org/research-central/hhs-info-central/> (last visited May 31, 2019).

1 <https://bit.ly/2VjFsVb>, thus admitting the Mandate was not the least restrictive means of achieving the
 2 government's interests.

3 The Supreme Court unanimously vacated the decisions of the Courts of Appeals of the Third, Fifth,
 4 Tenth, and D.C. Circuits, which had ruled in favor of the agencies. *Zubik*, 136 S. Ct. at 1561. It noted
 5 the “substantial” change in the government’s position and ordered that the parties should be “afforded
 6 an opportunity to arrive at an approach going forward” that would resolve the dispute. *Id.* at 1560. The
 7 Court thus ordered the government not to impose taxes or penalties on petitioners for failure to comply
 8 with the Mandate and remanded the cases.

9 Other injunctions forbid the federal government from enforcing the Mandate against all known
 10 religious objectors. Some of these were issued prior to the rules at issue in this case.⁴ Some, however,

12 ⁴ See, e.g., Injunction, *Am. Pulverizer Co. v. HHS*, No. 6:12-cv-03459 (W.D. Mo. Oct. 30, 2014), Dkt. 13 56; Injunction, *Annex Medical, Inc., v. Sebelius*, No. 0:12-cv-02804 (D. Minn. Aug. 19, 2015), Dkt. 76; 14 Amended Final Judgment, *Armstrong v. Sebelius*, No. 1:13-cv-00563 (D. Colo. Oct. 7, 2014), Dkt. 82; Injunction, *Autocam Corp. v. Sebelius*, No. 1:12-cv-01096 (W.D. Mich. Jan. 5, 2015), Dkt. 76; 15 Injunction, *Barron Indus., Inc. v. Sebelius*, No. 1:13-cv-01330 (D.D.C. Oct. 27, 2014), Dkt. 10; Consent Injunction, *Bick Holdings, Inc. v. HHS*, No. 4:13-cv-00462 (E.D. Mo. Nov. 18, 2014), Dkt. 24; Order, *Brandt, Bishop of the Roman Catholic Diocese of Greensburg v. Sebelius*, No. 2:14-cv- 16 00681 (W.D. Pa. Aug. 20, 2014), Dkt. 43; Injunction, *Briscoe v. Sebelius*, No. 1:13-cv-00285 (D. Colo. Jan. 27, 2015), Dkt. 70; *Catholic Diocese of Beaumont v. Sebelius*, 10 F. Supp. 3d 725 (E.D. Tex. 2014) (No. 1:13-cv-00709); Permanent Injunction, *C.W. Zumbiel Co. v. HHS*, No. 1:13-cv-01611 (D.D.C. Nov. 3, 2014), Dkt. 19; Order, *Conestoga Wood Specialties Corp. v. Sebelius*, No. 5:12-cv- 18 06744 (E.D. Pa. Oct. 2, 2014), Dkt. 82; Order, *Medford v. Sebelius*, No. 0:13-cv-01726 (D. Minn. Nov. 20, 2014), Dkt. 20; Order, *Doboszenski & Sons, Inc. v. Sebelius*, No. 0:13-cv-03148 (D. Minn. Nov. 18, 2014), Dkt. 15; Injunction, *Domino’s Farms Corp. v. Sebelius*, No. 2:12-cv-15488 (E.D. Mich. Dec. 3, 2014), Dkt. 54; *E. Tex. Baptist Univ. v. Sebelius*, 988 F. Supp. 2d 743, No. 4:12-cv- 20 03009 (S.D. Tex. 2013); Injunction, *Eden Foods, Inc. v. Sebelius*, No. 2:13-cv-11229 (E.D. Mich. Feb. 12, 2015), Dkt. 39; Order, *Eternal World Television Network v. U.S. Dep’t of Health & Human Servs.*, No. 14-12696 (11th Cir. May 31, 2016); Order, *Feltl & Co. v. Sebelius*, No. 0:13-cv-02635 (D. Minn. Nov. 26, 2014), Dkt. 15; Order, *Gilardi v. HHS*, No. 1:13-cv-00104 (D.D.C. Oct. 20, 2014), Dkt. 49; Injunction and Judgment, *Grote Indus., LLC v. Sebelius*, No. 4:12-cv-00134 (S.D. Ind. Apr. 30, 2015), Dkt. 66; Order, *Hall v. Sebelius*, No. 0:13-cv-00295 (D. Minn. Nov. 26, 2014), Dkt. 13; Injunction, *Hartenbower v. HHS*, No. 1:13-cv-02253 (N.D. Ill. Nov. 3, 2014), Dkt. 34; Order, *Hastings Chrysler Ctr., Inc. v. Sebelius*, No. 0:14-cv-00265 (D. Minn. Dec. 11, 2014), Dkt. 38; Order, *Hobby Lobby*

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10 *Stores, Inc. v. Sebelius*, No. 5:12-cv-01000, 2014 WL 6603399 (W.D. Okla. Nov. 19, 2014) (Dkt. 98);
11 Injunction, *Holland v. HHS*, No. 2:13-cv-15487 (S.D. W. Va. May 29, 2015), Dkt. 52; *Johnson Welded*
12 *Products, Inc. v. Sebelius*, No. 1:13-cv-00609, 2014 WL 5395775, (D.D.C. Oct. 24, 2014) (Dkt. 11);
13 Order of Injunction, *Korte v. HHS*, No. 3:12-cv-1072 (S.D. Ill. Nov. 7, 2014), Dkt. 89; *La. Coll. v.*
14 *Azar*, 38 F. Supp. 3d 766 (W.D. La. Aug. 13, 2014) (summary judgment and permanent injunction);
15 Injunction, *Lindsay v. HHS*, No. 1:13-cv-01210 (N.D. Ill. Dec. 3, 2014), Dkt. 50; Injunction, *M&N*
16 *Plastics, Inc. v. Sebelius*, No. 5:13-cv-14754 (E.D. Mich. Nov. 17, 2015), Dkt. 10; Order, *March for*
17 *Life v. Azar*, No. 1:14-cv-01149 (D.D.C. Aug. 31, 2015), Dkt. 31; Injunction and Judgment, *Mersino*
18 *Dewatering Inc. v. Sebelius*, No. 2:13-cv-15079 (E.D. Mich. Feb. 27, 2015), Dkt. 9; Injunction,
19 *Mersino Mgmt. Co. v. Sebelius*, No. 2:13-cv-11296 (E.D. Mich. Feb. 4, 2015), Dkt. 37; Order, *Midwest*
20 *Fastener Corp. v. Sebelius*, No. 1:13-cv-01337 (D.D.C. Oct. 24, 2014), Dkt. 21; Stipulated Order, *MK*
21 *Chambers Co. v. HHS*, No. 2:13-cv-11379 (E.D. Mich. Nov. 21, 2014), Dkt. 54; Permanent Injunction,
22 *Newland v. Sebelius*, No. 1:12-cv-01123 (D. Colo. Mar. 16, 2015), Dkt. 70; Injunction, *O'Brien v.*
23 *HHS*, No. 4:12-cv-00476 (E.D. Mo. Nov. 12, 2014), Dkt. 64; Order, *Randy Reed Auto., Inc. v. Sebelius*,
24 No. 5:13-cv-06117 (W.D. Mo. Nov. 12, 2014), Dkt. 29; Injunction, *Roman Catholic Archdiocese of*
25 *N.Y. v. Sebelius*, No. 1:12-cv-02542 (E.D.N.Y. Dec. 16, 2013), Dkt. 117; Order, *Sioux Chief MFG.*
26 *Co. v. Sebelius*, No. 4:13-cv-00036 (W.D. Mo. Nov. 12, 2014), Dkt. 19; Injunction, *SMA, LLC v.*
27 *Sebelius*, No. 0:13-cv-01375 (D. Minn. Nov. 20, 2014), Dkt. 16; Order, *Stewart v. Sebelius*, No. 1:13-
28 cv-01879 (D.D.C. Feb. 2, 2015), Dkt. 9; Order for Injunction, *Stinson Electric, Inc. v. Sebelius*, No.
29 0:14-cv-00830 (D. Minn. Nov. 18, 2014), Dkt. 18; Order, *Tonn & Blank Constr. LLC v. Sebelius*, No.
30 1:12-cv-00325 (N.D. Ind. Nov. 6, 2014), Dkt. 56; Order, *Tyndale House Publishers, Inc. v. Sebelius*,
31 No. 1:12-cv-01635 (D.D.C. Jul. 15, 2015), Dkt. 53; Injunction, *Weingartz Supply Co. v. Sebelius*, No.
32 2:12-cv-12061 (E.D. Mich. Dec. 31, 2014), Dkt. 98; Order, *Wieland v. HHS*, No. 4:13-cv-01577 (E.D.
33 Mo. Jul 21, 2016), Dkt. 87; Order, *Williams v. Sebelius*, No. 1:13-cv-01699 (D.D.C. Nov. 5, 2014),
34 Dkt. 11; Amended Order, *Willis & Willis PLC v. Sebelius*, No. 1:13-cv-01124 (D.D.C. Oct. 31, 2014),
35 Dkt. 17; Order, *Zubik v. Sebelius*, No. 2:13-cv-01459 (W.D. Pa. Dec. 20, 2013), Dkt. 81.

were issued after the IFRs were enjoined.⁵ Indeed, several injunctions have been entered in open-ended class or associational standing cases that allow new members to join.⁶ These injunctions continue to bind the agency defendants to this day.

C. Challenges to the IFRs

After years of unsuccessful attempts to justify the Mandate in court, in compliance with Congress's mandate that government "shall not" impose a substantial burden on religion, and in compliance with injunctions forbidding enforcement against religious and moral objectors, *see, e.g., Zubik*, 136 S. Ct. at 1561, the federal defendants issued two interim final rules providing that the Mandate will not be enforced against employers with religious or moral objections. 82 Fed. Reg. 47,792 (Oct. 13, 2017) (Fourth IFR); 82 Fed. Reg. 47,838 (Oct. 13, 2017) (Fifth IFR).⁷ The IFRs otherwise left the Mandate

⁵ See, e.g., Order, *Ass'n of Christian Sch. v. Azar*, No. 1:14-cv-02966 (D. Colo. Dec. 10, 2018), Dkt. 49; Order, *Ave Maria Sch. of Law v. Sebelius*, No. 2:13-cv-00795 (M.D. Fla. Jul. 11, 2018), Dkt. 68; Order, *Ave Maria Univ. v. Sebelius*, No. 2:13-cv-00630 (M.D. Fla. Jul. 11, 2018), Dkt. 72; Order, *Colo. Christian Univ. v. HHS*, No. 1:13-cv-02105 (D. Colo. Jul. 11, 2018), Dkt. 84; *Dobson v. Azar*, No. 13-cv-03326-REB-CBS (D. Colo. Mar. 26, 2019), Dkt. 61; Order, *Dordt Coll. v. Sebelius*, No. 5:13-cv-04100 (N.D. Iowa June 12, 2018), Dkt. 85; Permanent Injunction, *Geneva Coll. v. Sebelius*, No. 2:12-cv-00207 (W.D. Pa. Jul. 5, 2018), Dkt. 153; Permanent Injunction, *Grace Sch. v. Sebelius*, No. 3:12-cv-00459 (N.D. Ind. June 1, 2018), Dkt. 114; Order, *Little Sisters of the Poor v. Hagan*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt. 82; Permanent Injunction, *Sharpe Holdings, Inc. v. HHS*, No. 2:12-cv-00092 (E.D. Mo. Mar. 28, 2018), Dkt. 161; Order, *S. Nazarene Univ. v. Hagan*, No. 5:13-cv-01015 (W.D. Okla. May 15, 2018), Dkt. 109; Permanent Injunction, *Wheaton Coll. v. Azar*, No. 1:13-cv-08910 (N.D. Ill. Feb. 22, 2018), Dkt. 119.

⁶ See, e.g., *Reaching Souls Int'l, Inc. v. Azar*, No. 5:13-cv-01092, 2018 WL 1352186, at *2 (W.D. Okla. Mar. 15, 2018); Order, *Catholic Benefits Ass'n LCA v. Hagan*, No. 5:14-cv-00240 (W.D. Okla. Mar. 7, 2018), Dkt. 184 (granting permanent injunction of mandate to current and future nonprofit members of Catholic Benefits Association); Order, *Christian Emp's All. v. Azar*, No. 3:16-cv-00309 (D.N.D. May 15, 2019), Dkt. 53 (granting permanent injunction).

⁷ Many of the arguments presented here are relevant to both the religious and moral exemption, but the Little Sisters address only the religious exemption. Singular references to "IFR" or "Final Rule" are to that rule. The Little Sisters would only need to rely on the moral objector rule if the States argued, or the Court found, that the moral rule survives but the religious rule does not.

1 in place as to all employers previously covered. The IFRs also left in place the accommodation. 45
 2 C.F.R § 147.131. The IFRs were immediately challenged in this lawsuit and in others around the
 3 country.⁸ This Court entered a nationwide injunction preventing the implementation of the Fourth and
 4 Fifth IFRs on December 21, 2017 due to a lack of prior notice and comment. Order, Dkt. 105. That
 5 injunction was appealed to the Ninth Circuit, which held that the plaintiff States California, Delaware,
 6 Maryland, New York, and the Commonwealth of Virginia met the “relaxed” requirements for standing
 7 to bring the procedural claim on appeal. *California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018). The
 8 Court also ruled in favor of the States on their procedural claims, holding that the IFRs likely violated
 9 the notice and comment provisions of the APA. *Id.* at 575-78. The Ninth Circuit also held that a
 10 nationwide injunction was inappropriate and limited the injunction to the plaintiff States. *Id.* at 582-
 11 84.

12 **D. The Final Rule and ongoing proceedings**

13 The agencies received comments and reviewed them over a period of several months. They then
 14 finalized the religious exemption in a final rule that took effect on January 14, 2019. 83 Fed. Reg.
 15 57,536 (Nov. 15, 2018) (Final Rule). Following the publication of the Final Rule, the States submitted
 16 a second amended complaint joining more plaintiff States, including Connecticut, the District of
 17 Columbia, Hawaii, Illinois, Minnesota, North Carolina, Rhode Island, Vermont, and Washington. Dkt.
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19 ⁸ *ACLU v. Azar*, No. 4:17-cv-05772 (N.D. Cal.), dismissed without prejudice Nov. 2, 2018; *Campbell*
 20 *v. Trump*, No. 1:17-cv-02455 (D. Colo.), dismissed Sept. 11, 2018; *Massachusetts v. HHS*, No. 1:17-
 21 cv-11930 (D. Mass.), summary judgment granted in favor of defendants Mar. 12, 2018, vacated and
 22 remanded, 923 F.3d 209 (1st Cir. 2019); *Medical Students for Choice v. Azar*, No. 1:17-cv-02096
 23 (D.D.C.), dismissed without prejudice Feb. 2, 2018; *Pennsylvania v. Trump*, No. 2:17-cv-4540 (E.D.
 Pa. Jan. 13, 2019), preliminary injunction granted Dec. 15, 2017, preliminary injunction granted Jan.
 13, 2019, on appeal No. 17-3752 (3d Cir.); *Shiraef v. Azar*, No. 3:17-cv-00817 (N.D. Ind.), dismissed
 without prejudice Feb. 7, 2018; *Washington v. Trump*, No. 2:17-cv-01510 (W.D. Wash.), dismissed
 without prejudice Dec. 19, 2018.

1 170. The States brought a second motion for a preliminary injunction, arguing that the Final Rule
2 violates substantive provisions of the APA, and that the Final Rule is tainted by the lack of comment
3 on the IFRs. Dkt. 174. This Court granted that motion. Dkt. 234. The agencies and both Defendant-
4 Intervenors appealed the preliminary injunction to the Ninth Circuit, which will hear argument on June
5 6. *California v. Azar*, No. 19-15072 (9th Cir. docketed Jan. 14, 2019). Oregon moved separately to
6 intervene. Dkt. 210 (Jan. 7, 2019). The Court granted that motion. Dkt. 274 (Feb. 1, 2019). Oregon
7 submitted its own complaint, Dkt. 287 (Feb. 21, 2019), and filed a motion to be included in the Court's
8 preliminary injunction, which is pending. Dkt. 288, (Feb. 21, 2019). Oregon joined the States' motion
9 for summary judgment. The States have thus far submitted no evidence of any employer who will drop
10 coverage as a result of the Final Rule and identified no women who stand to lose coverage as a result
11 of the Final Rule.

ARGUMENT

I. The States lack Article III standing.

A. The States lack standing to bring Establishment Clause or Equal Protection claims.

In over a year and a half of litigation, the States have cited no authority for the idea that states can bring Establishment Clause claims against the federal government to challenge a religious accommodation. Since the States challenge a federal exemption rather than an expenditure, they cannot have offended observer or taxpayer standing in relation to the federal government.

19 Similarly, states are not “person[s]” under the Fifth Amendment capable of asserting an equal
20 protection claim. *Premo v. Martin*, 119 F.3d 764, 771 (9th Cir. 1997) (citing *South Carolina v.*
21 *Katzenbach*, 383 U.S. 301, 323-24 (1996)); *Bd. of Nat. Res. of State of Wash. v. Brown*, 992 F.2d 937,
22 942 (9th Cir. 1993) (“States as states clearly are not persons for Fifth Amendment purposes.”).

1 **B. The States lack injury in fact.**

2 The Plaintiff States have not submitted evidence sufficient to establish Article III standing at the
 3 summary judgment stage. In order to establish Article III standing, Plaintiffs cannot rely on “mere
 4 allegations,” but must provide “specific facts,” that show an injury, fairly traceable to the challenged
 5 action, that is redressable by a decision from the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561,
 6 (1992); *see also Braunstein v. Arizona Dep’t of Transp.*, 683 F.3d 1177, 1184 (9th Cir. 2012).⁹ The
 7 States present no additional evidence that they will be harmed by the Final Rules with their motion for
 8 summary judgment, much less that the alleged harms are attributable to the defendants. Instead, they
 9 continue to fail to identify any employers who are not protected by current court injunctions and who
 10 plan to take advantage of the Final Rules. They offer no “specific facts” at this stage to support their
 11 theory of harm. If, at this stage of the litigation, the States are still unable to identify a single employer
 12 who will drop coverage, or a single woman who will turn to the States to fund her coverage, this
 13 confirms what the Little Sisters said all along: the States’ alleged injury is too speculative to satisfy
 14 Article III standing. *See Opp’n to Mot. for Prelim. Inj.* at 6-10, Dkt. 75; Little Sisters’ Opening Br. at
 15 26-40, *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (No. 18-15144), Dkt. 13; Little Sisters’ Reply
 16 Br. at 27-34, *California*, 911 F.3d 558, Dkt. 90.

17 **C. The States’ claimed injury would not be redressable.**

18 Adding to the problems with the States’ alleged injury, an order enjoining the Final Rule would
 19 also not redress the claimed harm. Religious objectors can bring their own RFRA lawsuits and obtain
 20

21 ⁹ On a motion to dismiss, the court “accept[s] as true” the complaint’s allegations, and “construe[s]
 22 the complaint in favor of the complaining party.” *Warth v. Seldin*, 422 U.S. 490, 501 (1975). But the
 23 States lack standing under either standard, because they have “fail[ed] to allege an injury that fairly
 24 can be traced to [the agencies’] challenged action.” *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26,
 45 n. 25 (1976).

1 injunctions, given that the government has admitted that it has no compelling interest in enforcing the
 2 underlying mandate and cannot in good faith assert an affirmative defense they disagree with in court.
 3 Or they can join existing classes that already have injunctions against the mandate. *See supra* note 6.
 4 Or, since many religious employers have fewer than fifty employees, they can simply drop health
 5 insurance altogether. 26 U.S.C. § 4980H(c)(2).

6 Furthermore, before the Fourth IFR and the Final Rule were issued, the regulations contained
 7 variations from the mandate in the form of an exemption for churches and integrated auxiliaries and a
 8 separate so-called “accommodation” for other religious employers. That accommodation is central to
 9 the States’ case, because without it, the mandate violates *Hobby Lobby*. *Hobby Lobby*, 573 U.S. 682.
 10 Yet—according to the States’ reasoning—the earlier exemption and accommodation violate the APA.
 11 The States argue that the ACA authorized the agencies to determine only “*which* additional preventive
 12 care services” must be covered, not who must provide the coverage, and that the agencies do not have
 13 statutory authority to create exemptions to the preventive services mandate. Mot. 17 (emphasis added).
 14 But the States also request that the Court replace the Final Rule with the mandate *as it existed before*
 15 *the IFRs*.

16 That relief—the revival of the prior mandate regime, complete with the “accommodation” and
 17 religious employer exemption—cannot be entered consistent with an order that the Final Rules are
 18 insufficient for the same reasons that regime is. If HRSA has no authority to decide who must provide
 19 the coverage, then it surely has no authority to exempt some employers, “accommodate” others, and
 20 impose new obligations on insurers and TPAs to comply in their place. Yet that is precisely the regime
 21 the States ask this Court to reimpose.

1 For these reasons, the States lack standing, and the Second Amended Complaint and Complaints
 2 in Intervention should be dismissed, or the Court should enter summary judgment in favor of
 3 Defendants.

4 **II. The Plaintiffs cannot prevail on their claims that the Final Rule is substantively invalid.**

5 **A. The Final Rule does not violate the ACA.**

6 *1. The agencies may make exemptions from a contraceptive mandate that they were never
 obligated to create.*

7 The States argue that the Final Rule is contrary to law, reasoning that the agencies lacked authority
 8 to create the religious exemption from the contraceptive mandate. But the ACA did not require any
 9 contraceptive mandate in the first place, which makes the States' anti-exemption argument absurd.
 10 The relevant statutory section says nothing about contraception. The ACA merely requires certain
 11 employers to offer "a group health plan" that provides coverage for women's "preventive care and
 12 screenings." 42 U.S.C. § 300gg-13(a)(4); 26 U.S.C. § 9815; 29 U.S.C. § 1185d. Congress did not
 13 specify what "preventive care" means, but instead delegated that task to HRSA. HRSA, in turn, had
 14 discretion to articulate "guidelines" the agency wished to "support[]" for this purpose. 42 U.S.C.
 15 § 300gg-13(a)(4); *see* 2011 Preventive Services Guidelines.

16 Thus, HRSA was under no obligation to include contraceptives in the preventive services
 17 regulations at all, much less all FDA-approved contraceptives. HRSA could have limited the
 18 guidelines to other preventive services such as domestic violence screening and well-woman visits,
 19 made no mention of contraceptives, and have still faithfully implemented the "preventive care"
 20 requirement. *See* 42 U.S.C. § 300gg-13(a)(4); 2011 Preventive Services Guidelines.

21 The States argue that the language of the statute did not include delegation of authority to create
 22 exemptions from the preventive care mandate, Mot. 17, but if Congress meant for HRSA to simply
 23

1 create a list of covered items from which there could be no deviation, it could have said so. It did just
 2 this for subsections (1) and (2) of Section 300gg-13:

- 3 (1) evidence-based items or services that have in effect a rating of “A” or “B” in the current
 recommendations of the United States Preventive Services Task Force;
- 4 (2) immunizations that have in effect a recommendation from the Advisory Committee on
 Immunization Practices of the Centers for Disease Control and Prevention with respect to
 the individual involved;

6 42 U.S.C. § 300gg-13. These provisions require coverage of all “items or services” on a particular list,
 7 or all immunizations, if recommended “with respect to the individual involved.” *Id.* The language used
 8 in (4) is markedly different: “such additional preventive care and screenings . . . (1) as provided for in
 9 comprehensive guidelines” from HRSA. 42 U.S.C. § 300gg-13(4). Since it is “presume[d] that the
 10 ordinary meaning of the words chosen by Congress accurately express its legislative intent,” the
 11 distinction between these provisions indicates a broader grant of discretion to HRSA in crafting the
 12 regulations. *Santiago Salgado v. Garcia*, 384 F.3d 769, 771 (9th Cir. 2004) (internal quotation marks
 13 and citation omitted).

14 Under the States’ interpretation, the agencies had no flexibility in determining how to apply the
 15 preventive services mandate. Mot. 17-18. But HHS has used its discretion to delimit the guidelines
 16 since the earliest implementation of the preventive services mandate, and not just on contraceptives.
 17 For all preventive services, HRSA has exercised discretion to “specify the frequency, method,
 18 treatment, or setting for the provision of that service,” and has directed that if such information is not
 19 specified, “the plan or issuer can use reasonable medical management techniques to determine any
 20 coverage limitations.” Centers for Consumer Information & Insurance Oversight, *Affordable Care Act*
 21 *Implementation FAQs – Set 12*, Centers for Medicare & Medicaid Services,
 22 <https://go.cms.gov/2I54sZV> (last visited May 31, 2019). HRSA has also created age limits in its
 23 recommendations. For example, in average-risk women, HPV screenings are only covered for those

1 age 30 and older, and mammograms are only covered for those age 40 and older. States' Ex. 20 (D9
 2 666668) (HRSA, *Women's Preventive Services Guidelines*, U.S. Dep't of Health & Human Servs.
 3 (Oct. 2017)). HRSA has been exercising its statutory discretion to delimit coverage requirements for
 4 years, and the States have not claimed that it is contrary to law to limit preventive services by age (a
 5 limitation not found in Section 300gg-13(a)(4)), nor that it is improper to utilize "reasonable medical
 6 management techniques" to determine exclusions from coverage.

7 The upshot is that HRSA could have required coverage of some contraceptives and not others,
 8 permitted employers to exclude coverage of some contraceptives due to cost considerations (which it
 9 in fact does),¹⁰ or determined that a contraception mandate was unnecessary due to widespread
 10 coverage pre-dating the ACA. Indeed, since the listing of contraceptives itself is not in the Code of
 11 Federal Regulations and has never been subject to formal rulemaking, HRSA could edit its website
 12 tomorrow to eliminate some or all contraceptives from the list, and the States would have no recourse.
 13 To claim that the agencies have no authority to create exemptions from the mandate in these
 14 circumstances is weaving new administrative law from whole cloth.

15 The States proceed as if those guidelines must delineate an inflexible list of covered services. See
 16 Mot. 17-18. In reality, the guidelines specify *what* preventive services must be covered and to *whom*
 17 those services should apply. The "comprehensive guidelines" for mandatory minimum coverage for
 18 children's preventive care, sharing a subsection and a "shall" with the women's preventive care section,
 19 provide an analogue. *Compare* 42 U.S.C. § 300gg-13(a)(3) *with* (a)(4). Those guidelines make a
 20 variety of age- and individual-circumstance-based recommendations which note that "variations,
 21

22 ¹⁰ Employers may exclude more expensive contraceptives if they cover a cheaper contraceptive in the
 23 same category. See Centers for Consumer Information & Insurance Oversight, *Affordable Care Act
 Implementation FAQs – Set 12*, Centers for Medicare & Medicaid Services,
<https://go.cms.gov/2I54sZV> (last visited May 31, 2019).

1 taking into account individual circumstances, may be appropriate,” and “[recommended procedures]
 2 may be modified, depending on entry point into schedule and individual need.” Bright
 3 Futures/American Academy of Pediatrics, Recommendations for Preventive Pediatric Health Care
 4 (2019), https://www.aap.org/en-us/Documents/periodicity_schedule.pdf (children’s preventive care
 5 guidelines).

6 Nowhere does the statute tell HRSA to include contraceptives in the guidelines; it would be strange
 7 indeed if the agencies had the discretionary power to create a nationwide contraceptive mandate but
 8 not the discretionary power to frame that mandate to balance competing interests. Indeed, that is how
 9 HRSA has understood its discretion from Day 1. *See* 76 Fed. Reg. at 46,623 (“In the Departments’
 10 view, it is appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the
 11 religious beliefs of certain religious employers if coverage of contraceptive services were required in
 12 the group health plans in which employees in certain religious positions participate.”).

13 The States argue that it would “be untenable practically” for Congress to “enumerate the specific
 14 services contained” in the mandate. Mot. 17 n.22. Not so. Just *two subsections* away from the
 15 preventive services mandate, Congress prohibited cost-sharing requirements for “evidence-based
 16 items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United
 17 States Preventive Services Task Force” or “immunizations that have in effect a recommendation from
 18 the [relevant advisory committee] with respect to the individual involved.” 42 U.S.C. § 300gg-
 19 13(a)(1)-(2). Congress could have also guaranteed women “all FDA-approved contraceptives.” But
 20 Congress instead permitted HRSA to balance competing interests like expanding contraceptive access
 21 and protecting religious exercise.

22 The States point to an entirely unrelated section prohibiting the government from punishing,
 23 among others, hospitals that do not conduct “mercy killing[s],” 42 U.S.C. § 18113, from which they

1 derive the negative implication that there are no other statutory exemptions for religious entities in the
 2 entire ACA. Mot. 18. Though the ACA nowhere mandates euthanasia coverage (the practice was
 3 illegal in forty-eight states at the time the ACA was enacted), the States call section 18113 a “statutory
 4 exemption” for “religious object[ors].” *Id.*

5 That towering inference misapplies the negative implication canon, which applies when the
 6 exception specified can reasonably be thought to express *all* exceptions to the prohibition involved.
 7 See, e.g., *United States v. Giordano*, 416 U.S. 505, 514 (1974) (executive assistant cannot exercise
 8 wiretap authority delegated to the “Attorney General” and “any Assistant Attorney Generally specially
 9 designated by the Attorney General”); see also A. Scalia & B. Garner, *Reading Law* 107 (2012).
 10 Section 18113 has nothing to do with preventive care or HRSA’s discretion to craft preventive services
 11 policy, and therefore does not foreclose HRSA’s discretion to not impose contraceptive coverage
 12 obligations on religious entities, particularly when RFRA explicitly applies to every government
 13 “agency, instrumentality, and official.” 42 U.S.C. § 2000bb-2(1).¹¹

14 The better reading of the statute—shared by both administrations to oversee the ACA—is that
 15 HRSA can decide not to impose certain coverage requirements on religious entities, provided that the
 16 scope of the exemption is not arbitrary and capricious. Though the States insist that arbitrary-and-
 17 capricious review is not a meaningful limit, Mot. 20 (arguing “[u]nder their interpretation, [the

19 ¹¹ Equally meritless is any inference from Congress’s decision to not pass the Conscience Amendment.
 20 See Mot. 18-19. Congress also declined to pass legislation declaring that RFRA did *not* apply to
 21 portions of the mandate. See Protect Women’s Health From Corporate Interference Act of 2014,
 22 S. 2578, 113th Cong. (2014), <https://www.congress.gov/bill/113th-congress/senate-bill/2578/actions>;
 23 Protect Women’s Health From Corporate Interference Act of 2014, H.R. 5051, 113th Cong. (2014)
<https://www.congress.gov/bill/113th-congress/house-bill/5051/actions>. Such failed legislative
 proposals “lack[] persuasive significance because several equally tenable inferences may be drawn
 from such inaction.” *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S.
 164, 187 (1994) (citation omitted).

1 agencies] . . . could exempt all employers from” section 300gg-13(a)(4)), they offer no defense of the
 2 religious exemption imposed at the same time as the Mandate.¹²

3 2. *The States’ reasoning, if accepted, would also invalidate the preexisting religious employer
 4 exemption and “accommodation.”*

5 The States’ APA argument also proves too much. If the agencies had authority only to determine
 6 “which additional preventive care services” must be covered, the agencies lacked the authority to issue
 7 the 2011 religious employer exemption, or to create a complex “accommodation” system, upon which
 8 the States rely for their analysis. Mot. 17 (emphasis added); 76 Fed. Reg. at 46,626. If HHS had no
 9 power to exempt some employers from the Mandate, then it has no choice but to impose the Mandate
 10 on houses of worship.

11 Under the States’ theory of agency authority, the religious employer exemption cannot be cured
 12 simply because it refers to the Internal Revenue Code. *See* Mot. 9. Nothing in the ACA incorporates
 13 the Internal Revenue church exemption into the preventive services mandate. Nor is there anything
 14 special about the Internal Revenue Code: federal law has different ways to identify religious
 15 organizations. *See, e.g.*, 42 U.S.C. § 290kk (“a nonprofit religious organization”); 10 C.F.R. § 5.205
 16 (educational institutions can self-identify as religious organizations). And federal law contains a
 17 variety of religious exemptions, any of which the agencies could have selected to rely upon here, such
 18 as Title VII’s religious employer exemption or Title IX’s exemption for religious educational
 19 institutions.¹³

20 ¹² On appeal, the States argued that the church exemption is not arbitrary and capricious because it is
 21 “narrow[]” and is mirrored by a provision in the Internal Revenue Code. States’ Br. at 35, *California
 v. Azar*, Nos. 19-15072 (9th Cir. Apr. 15, 2019).

22 ¹³ *See, e.g.*, 42 U.S.C. § 2000e-1(a) (“This subchapter shall not apply to . . . a religious corporation,
 23 association, educational institution, or society with respect to the employment of individuals of a
 particular religion to perform work connected with the carrying on by such corporation, association,

The States offer no reason why the agencies would have authority to create a religious employer exemption based on a snippet of unrelated tax code (which by no means purports to define religious organizations), *see* 26 U.S.C. § 6033(a)(3)(C) (referring in the same section to “religious organization” as a different category), but lack the authority to adopt the exemption in the Final Rule. Indeed, the States attempted to defend the church exemption at the preliminary injunction stage and on appeal, but they now make no arguments that the church exemption is valid at all. *Compare* Mot. 9 (“In creating the church exemption, Defendants did not identify any provision in the ACA authorizing them to create such an exemption.”), *with* States’ Br. at 35-36, *California v. Azar*, No. 19-15072 (9th Cir. Apr. 15, 2019), Dkt. 72 (church exemption is “narrowly crafted and tethered to the Internal Revenue Code” and “based on . . . governmental recognition of a particular sphere of autonomy for houses of worship.”) (quoting 80 Fed. Reg. at 41,325); Reply ISO Mot. Prelim. Inj. at 9, Dkt. 218 (same).

Perhaps the States recognized that their theories are insufficient. A reference to the religious employer doctrine in *Hosanna-Tabor* is a poor fit for justifying the religious exemption since it *would* cover religious orders like the Little Sisters and other groups not previously exempt, and would *not* function as a blanket exception for all church employees. *See Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171, 190-94 (2012) (discussing indicia of ministerial role). And whether “churches are more likely to hire co-religionists,” States’ Br. at 35-36, *California*, No. 19-15072, Dkt. 72, is irrelevant to the underlying question of authority to create a regulatory exception. In any case, if the Mandate violates the Free Exercise Clause when applied to all employers, and since the States think the agency has no statutory authority to make distinctions, the only plausible legal

22 educational institution, or society of its activities.”); 20 U.S.C. § 1681(a)(3) (“this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization”); 42 U.S.C. § 290kk(c)(6) (“The term ‘religious organization’ means a nonprofit religious organization.”).

1 result of the States' argument would be that the agencies are barred from having any contraceptive
 2 mandate at all.

3 Nor do the agencies explain how the federal government could justify the so-called
 4 accommodation under their theories. The agencies cannot simultaneously lack power to make
 5 exemptions from the Mandate and also offer an accommodation that allows objectors to "opt out" of
 6 that Mandate. *See infra* Part II.A.3.b (substantial burden); Mot. 10, 25. Either the accommodation
 7 itself is an exemption (and therefore unlawful in the States' view because the agencies lack authority
 8 to create exemptions) or the accommodation is not a pure "opt out" but a separate obligation. The
 9 States' analysis relies on the accommodation in its determination that the Final Rule is not required
 10 by RFRA. But if the accommodation is really an "opt out," the States have offered no explanation as
 11 to how the agencies had authority to implement it under the ACA, but somehow lacked authority to
 12 issue the Final Rule at issue here.

13 Further, if the States prevail, the underlying Mandate would be impermissible under the Free
 14 Exercise and Establishment Clauses, which prohibit the government from making such "explicit and
 15 deliberate distinctions between different religious organizations." *Larson v. Valente*, 456 U.S. 228,
 16 246 n.23 (1982) (striking down laws that created differential treatment between "well-established
 17 churches" and "churches which are new and lacking in a constituency"). In that system, some religious
 18 organizations get exemptions (primarily churches and their "integrated auxiliaries"), and some do not.
 19 That rule exempts religious orders which engage in what the government deems "exclusively religious"
 20 activities. *See* 78 Fed. Reg. at 39,874 (limiting exemption to the "exclusively religious activities of
 21 any religious order"). But it does not exempt religious orders that, because of their faith, engage in
 22 activities the government deems not "exclusively religious," such as serving the elderly poor.

1 By preferring certain churches and religious orders to other types of religious orders and
 2 organizations, the mandate inappropriately “interfer[es] with an internal . . . decision that affects the
 3 faith and mission” of a religious organization. *Hosanna-Tabor*, 565 U.S. at 190. Doing so also requires
 4 illegal “discrimination . . . [among religious institutions] expressly based on the degree of religiosity
 5 of the institution and the extent to which that religiosity affects its operations[.]” *Colo. Christian Univ.*
 6 *v. Weaver*, 534 F.3d 1245, 1259 (10th Cir. 2008) (applying *Larson* to invalidate distinction between
 7 “sectarian” and “pervasively sectarian” organizations). And it does all of this when discriminating
 8 *between religious organizations that all qualify for the ministerial exception upon which the States*
 9 *base their argument*. *Shaliehsabou v. Hebrew Home of Greater Washington, Inc.*, 363 F.3d 299, 310
 10 (4th Cir. 2004) (holding that a religious entity qualifies for the ministerial exception “whenever that
 11 entity’s mission is marked by clear or obvious religious characteristics”). This Court cannot require
 12 the government to enforce an underlying regulation that, under the same reasoning by which it strikes
 13 down the current regulations, is unlawful.

14 3. *The agencies are permitted to issue the Final Rule to comply with RFRA.*

15 Faced with dozens of injunctions and multiple Supreme Court orders preventing them from
 16 enforcing the underlying mandate—which was the exact state of play when the Supreme Court vacated
 17 the appellate rulings in *Zubik*—the agencies could not be expected to maintain a rule that violated all
 18 of those injunctions, much less to continue advancing an affirmative defense of strict scrutiny they no
 19 longer believed. Their resulting attempt to comply with the Religious Freedom Restoration Act and
 20 stop asserting that affirmative defense is perfectly compatible with agencies’ obligation and authority
 21 to interpret their own rules in accordance with Congressional commands.

1 a. RFRA applies broadly to federal laws and federal agencies.

2 RFRA requires that the federal government “shall not substantially burden a person’s exercise of
 3 religion” unless doing so is the “least restrictive means” of advancing a “compelling governmental
 4 interest.” 42 U.S.C. § 2000bb-1(a)-(b). RFRA is not just a judicial remedy. Instead, it constrains every
 5 “agency,” “all Federal law, and the implementation of that law, whether statutory or otherwise,”
 6 including the agencies’ actions under the ACA. 42 U.S.C. §§ 2000bb-2, 2000bb-3. Simply put,
 7 whenever the federal government acts, it must obey RFRA.

8 b. The Mandate as it existed before the Fourth IFR violates RFRA and the Constitution.

9 In enacting RFRA, Congress also made clear that “religious exercise” is a broad term,
 10 encompassing “any exercise of religion.” 42 U.S.C. § 2000cc-5. Religious exercise includes “not only
 11 belief and profession but the performance of (or abstention from) physical acts’ that are ‘engaged in
 12 for religious reasons.’” *Hobby Lobby*, 573 U.S. at 710 (quoting *Emp’t Div. v. Smith*, 494 U.S. 872,
 13 877 (1990)).

14 ***Substantial burden.*** The substantial burden inquiry of RFRA is a simple two-part question:
 15 whether a religious belief is sincerely held and, if so, whether the government is “putting substantial
 16 pressure on an adherent” to act contrary to that belief. *Thomas v. Review Bd.*, 450 U.S. 707, 717-18
 17 (1981); see *Sherbert v. Verner*, 374 U.S. 398, 404 (1963) (“the pressure upon [a Seventh-day
 18 Adventist] to forego [abstaining from Saturday work] is unmistakable”); see also *Hobby Lobby*, 573
 19 U.S. at 695 n.3 (RFRA restored “*Sherbert* line of cases” and arguably “provide[s] even broader
 20 protection”).

21 The Little Sisters and other religious groups exercise religion by providing health insurance that
 22 complies with their religious beliefs. See Decl. of Mother Superior McCarthy ¶¶ 35-51, Dkt. 38-3. The
 23 States concede that these groups have a sincere religious objection to complying with the

1 “accommodation.” *Id.* ¶¶ 35-38; Mot. 22 (“The States do not question the sincerity of religious
 2 employers’ beliefs”). The States’ substantial burden analysis, however, relies on a novel interpretation
 3 of RFRA. The States argue that “sincerely held religious beliefs cannot—in and of themselves—
 4 answer the legal question of whether a law imposes a substantial burden under RFRA.” Mot. 22. But
 5 no one argues otherwise. Nor have the defendants argued that courts should “treat sincerely held
 6 beliefs and substantial burden as one and the same.” Mot. 24.

7 While it is of course true that courts and government cannot second-guess whether a particular
 8 religious belief is “correct,” the substantial burden inquiry focuses not on the “correctness” of a
 9 believer’s view that she cannot engage in certain conduct, but rather on the coercive force applied by
 10 the government. As the States acknowledge, once a concededly-sincere religious belief is established
 11 (as here), the question is whether the religious objectors are “coerced to act contrary to their religious
 12 beliefs by the threat of civil or criminal sanctions,” Mot. 21 (quoting *Navajo Nation v. U.S. Forest*
 13 *Serv.*, 535 F.3d 1058, 1069-70 (9th Cir. 2008) (en banc)).

14 Here, the accommodation depends on religious objectors contracting with their insurer or TPA to
 15 provide contraceptive coverage through their own plan infrastructure. Failure to comply with the
 16 mandate, either outright or via the accommodation, would result in large fines under 26 U.S.C.
 17 § 4980D (\$100/day per person) and 26 U.S.C. § 4980H(c)(1) (\$2000 per employee, per year)—the
 18 same fines that constituted a substantial burden in *Hobby Lobby*. 573 U.S. at 691 (“If these
 19 consequences do not amount to a substantial burden, it is hard to see what would.”). For the Little
 20 Sisters, that penalty would add up to \$3 million per year. Decl. of Mother Superior McCarthy, Dkt.
 21 38-3, ¶¶ 40-43. This is no “de minimis burden.” Mot. 26 (quoting *Eternal Word Television Network,*
 22 *Inc. v. HHS*, 818 F.3d 1122, 1150 (11th Cir. 2016), *vacated*, 2016 WL 11503064 (11th Cir. May 31,
 23 2016), *modified*, 2016 WL 11504187 (11th Cir. Oct. 3, 2016)); *see Hobby Lobby*, 573 U.S. at 726

1 (“Because the contraceptive mandate forces them to pay an enormous sum of money” for following
 2 their beliefs, “the mandate clearly imposes a substantial burden on those beliefs.”).

3 Rather than address the burden’s magnitude, the States argue that there is no substantial burden
 4 because “the accommodation process meticulously separates the employer’s health plan from any
 5 involvement in the provisions of contraceptive coverage.” Mot. 26. As the States see it, the Little
 6 Sisters just *should not* believe that participation in the system violates their faith, because the coverage
 7 is separate in a way that *should* alleviate the Sisters’ moral qualms. But this argument is akin to telling
 8 an Orthodox Jew that it is okay to flip a light switch she feels forbidden from flipping on the Sabbath.
 9 The States offer no authority for the notion that courts can second-guess a believer’s understanding
 10 that conduct is forbidden to her.

11 But in any case, despite using the word “separate,” Mot. 26, the States actually do not dispute the
 12 crucial fact that the accommodation works by using the employer’s plan. Religious objectors are
 13 required to execute Form 700, obligating their insurer to provide contraceptives to their employees
 14 through their plan infrastructure. 45 C.F.R. § 147.131(d). Or they must alternately inform HHS in
 15 writing not only of their religious objection, but also of the “name and type” of their plan, along with
 16 contact information for the health insurance issuers, and must keep HHS updated with changes to that
 17 information. 45 C.F.R. § 147.131(d)(1)(ii). In the case of religious entities with a self-insured plan—
 18 that is, a plan where the financial risk of claims is not borne by an insurance company—the notification
 19 via Form 700 or directly to HHS serves to “designate the relevant [TPA] as plan administrator,” a role
 20 a TPA does not normally have, and that requires legal authority from the employer, such that the
 21 notification becomes “an instrument under which the plan is operated.” 79 Fed. Reg. at 51,095. That
 22 is not simply “opting out.” Mot. 21. It is using legal authority to authorize and obligate a TPA to use
 23 the religious organization’s plan to provide coverage.

1 Regardless of the plan type, the regulations themselves announced that they relied on the
 2 employer’s “coverage administration infrastructure” to achieve the Mandate’s coverage goal. 80 Fed.
 3 Reg. 41,318, 41,328 (July 14, 2015). The third-party administrator would contact all plan participants,
 4 identify them by “payroll location,” and perform “[o]ngoing, nightly feeds” of information. Joint
 5 Appendix at 1220-22 (Guidestone Declaration), *Zubik*, 136 S. Ct. 1557, <https://bit.ly/2EOfljQ>; *see also*
 6 80 Fed. Reg. at 41,328-29 (acknowledging the plan information is used to “verify the identity” of
 7 beneficiaries and “provide formatted claims data for government reimbursement”).

8 Religious employers making use of the accommodation are thus forced to maintain a health plan
 9 infrastructure that includes the very coverage the employer finds religiously objectionable. *See* 78 Fed.
 10 Reg. at 39,876 (“plan participants and beneficiaries (and their health care providers) do not have to
 11 have two separate health insurance policies (that is, the group health insurance policy and the
 12 individual contraceptive coverage policy”). As the agencies and the States have conceded, “the
 13 coverage provided by the TPA is, as a formal ERISA matter, part of the same ‘plan’ as the coverage
 14 provided by the employer.” Br. for the Resp’ts at 38, *Zubik*, 136 S. Ct. 1557 (citation omitted),
 15 <https://bit.ly/2DiCj32>; States’ Br. at 46-47, *California*, No. 19-15072, Dkt. 72 (coverage is “part of
 16 the same ERISA plan”).

17 That is why Solicitor General Verrilli conceded that contraceptive coverage must be “part of the
 18 same plan as the coverage provided by the employer,” Br. for the Resp’ts at 38, *Zubik*, 136 S. Ct. 1557
 19 (internal quotations marks and citation omitted), <https://bit.ly/2DiCj32>; Tr. of Oral Arg. at 60-61,
 20 *Zubik*, 136 S. Ct. 1557, <https://bit.ly/2VklhFx> (Chief Justice Roberts: “You want the coverage for
 21 contraceptive services to be provided, I think as you said, seamlessly. You want it to be in one
 22 insurance package. . . . Is that a fair understanding of the case?”; Solicitor General Verrilli: “I think it
 23 is one fair understanding of the case.”). The Supreme Court itself recognized the government’s

1 “substantial clarification and refinement” in its position, *Zubik*, 136 S. Ct. at 1560, which is why it
 2 makes no sense for the States to rely on pre-*Zubik* courts of appeals decisions that were vacated as a
 3 result of *Zubik*. *See Mot.* 21.

4 Consistent with their concessions in *Zubik*, the agencies themselves now concede that forcing
 5 religious groups to comply with the accommodation “constituted a substantial burden” on religious
 6 exercise. 83 Fed. Reg. at 57,546. That explains why federal courts have awarded at least 14
 7 injunctions—not consent decrees—to religious objectors since *Zubik*.¹⁴ *See infra* Part II.A.3.c. Each
 8 injunction required an Article III judge to determine that the movant had made “a clear showing” that
 9 the law required that “extraordinary and drastic remedy.” *Mazurek v. Armstrong*, 520 U.S. 968, 972
 10 (1997).

11 The States thus have not shown that the Little Sisters are *factually* mistaken that the
 12 accommodation requires their assistance; they have only argued that the Little Sisters are *morally*
 13 mistaken about what constitutes complicity. And civil courts do not decide theological questions. *See,*
 14 *e.g.*, *Thomas*, 450 U.S. at 715-16 (“it is not for us to say that the line [plaintiff] drew was an
 15 unreasonable one”).

16 **Strict scrutiny.** Under RFRA, Congress permitted agencies to impose substantial burdens on
 17 religion only where they could prove that imposing the burden on a particular person was the least
 18 restrictive means of advancing a compelling government interest. 42 U.S.C. § 2000bb-1. Here, the
 19 government cannot carry that burden and, to its credit, has finally stopped trying to assert that

22 ¹⁴ The States refer to “stipulated” injunctions. Mot. 46. There is no such thing. Unlike a dismissal—
 23 which can in some situations be stipulated—an *injunction* necessarily requires independent judicial
 24 decisionmaking, since Article III power stands behind the order. That is why Rule 65 requires a court
 in “[e]very order granting an injunction . . . [to] state the reasons why it issued.” Fed. R. Civ. P. 65.

1 affirmative defense. *See* 83 Fed. Reg. at 57,546-49. The States’ attempt to revive the government’s
 2 interest on its behalf fails.

3 The States ask the Court to hold that “seamless access to contraceptive coverage is a compelling
 4 government interest,” Mot. 26, which they define as coverage “without cost-sharing or additional
 5 logistical or administrative hurdles,” Mot. 29. This interest—precluding *any* accommodation that
 6 could require a patient to fill out additional paperwork—is far more prescriptive than the interest
 7 discussed in the States’ cited cases, that is, “a compelling interest in facilitating access to
 8 contraception.” Mot. 27 (quoting *Priests for Life v. HHS*, 808 F.3d 1, 15 (D.C. Cir. 2015) (Kavanaugh,
 9 J., dissenting from denial of rehearing)). The States are attempting to bootstrap their preferred *means*
 10 into a compelling interest. But means cannot serve as ends for purposes of strict scrutiny, regardless
 11 of the context.

12 Moreover, the States cannot impose a compelling interest on the government which it does not
 13 itself recognize. RFRA permits “Government” to impose a substantial burden “only if *it* demonstrates”
 14 that strict scrutiny is satisfied—not an interested third party. 42 U.S.C. §§ 2000bb-1(b), 2000bb-2(1)
 15 (emphasis added). Even so, the States can hardly argue a compelling interest when some of them have
 16 adopted no contraceptive mandate at all—like the ones 28 states adopted prior to *Hobby Lobby*. Br.
 17 for the Resp’ts at 64, *Zubik*, 136 S. Ct. 1557, <https://bit.ly/2DiCj32>.

18 However the interest is defined, the government’s interest in requiring employers to provide
 19 contraceptives cannot be “compelling” since small businesses, grandfathered plans, churches, and
 20 government-sponsored plans are exempt. These existing exemptions do “appreciable damage” to any
 21 alleged interest in universal seamless coverage, showing that it cannot be an interest “of the highest
 22 order.” *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546-47 (1993)
 23 (internal quotations marks and citation omitted). For example, the Obama Administration defended its
 24

1 decision to exempt grandfathered plans because the affected women would have many other avenues
 2 to obtain coverage, including “through a family member’s employer, through an individual insurance
 3 policy purchased on an Exchange or directly from an insurer, or through Medicaid or another
 4 government program”—that is, non-seamless means. Br. for the Resp’ts at 65, *Zubik*, 136 S. Ct. 1557,
 5 <https://bit.ly/2DiCj32>. Similarly, the government argued that the grandfathering exemption—which
 6 has covered over 49 million people, *Hobby Lobby*, 573 U.S. at 700—did not undercut the
 7 government’s interests because “*most* women currently covered under grandfathered plans likely have
 8 (and will continue to have) *some* contraceptive coverage.” Br. for the Resp’ts at 64, *Zubik*, 136 S. Ct.
 9 1557 (emphasis added), <https://bit.ly/2DiCj32>. These concessions are partly why the Supreme Court
 10 remanded *Zubik* and why the government subsequently lost every case.¹⁵

11 Even if there were a compelling interest in seamless access, the accommodation would fail strict
 12 scrutiny because the government has alternatives to the forced collaboration of nuns. As the Supreme
 13 Court explained, “[t]he most straightforward way” of “guaranteeing cost-free access to the [relevant]
 14 contraceptive methods . . . would be for the Government to assume the cost.” *Hobby Lobby*, 573 U.S.
 15 at 728. And here, the government is already attempting to provide Title X funded contraceptives for
 16 women whose employers conscientiously object to contraceptive coverage. 84 Fed. Reg. 7714, 7734
 17 (Mar. 4, 2019) (enjoined on unrelated grounds, *see, e.g.*, Opinion and Order, *Oregon v. Azar*, No. 6:19-
 18 cv-00317 (D. Or. Apr. 29, 2019), Dkt. 142; Order, *Washington v. Azar*, No. 1:19-cv-03040 (E.D. Wash.
 19 Apr. 25, 2019), Dkt. 54; *see also* Order, *California v. Azar*, No. 3:19-cv-01184 (N.D. Cal. Apr. 26,
 20 2019), Dkt. 103 (state-wide injunction)).

21
 22 ¹⁵ See Mark L. Rienzi, *Fool Me Twice: Zubik v. Burwell and the Perils of Judicial Faith in*
 23 *Government Claims*, 2016 Cato Sup. Ct. Rev. 123 (2015-2016) (detailing concessions leading to the
Zubik remand).

The States find fault with these efforts because they involve “discretion[]” on the part of Title X projects (many administered by the States’ own *amici* like Planned Parenthood). But this misses the mark: what matters is not whether the States agree any current program is a perfect substitute, but whether less restrictive alternatives are *available*. Mot. 14 n.19. The States themselves attest to a range of state programs that provide contraceptives. The very existence of those programs proves that a plan run by nuns is not the least restrictive means of distributing contraceptives (which is presumably why neither the federal government nor the States ever thought of such a scheme before 2012).

The States also suggest that RFRA only allows accommodations that could burden third parties if “borne by the government or society as a whole.” Mot. 25. *Hobby Lobby* answers this objection in full, explaining that “it could not reasonably be maintained that any burden on religious exercise . . . is permissible under RFRA so long as the relevant legal obligation requires the religious adherent to confer a benefit on third parties.” 573 U.S. at 729 n.37. Otherwise, the Court explained, Muslim supermarkets could be mandated to sell alcohol or Jewish restaurants mandated to open on Saturdays for others’ benefit, with no protection under RFRA. *Id.*

Here, the “third-party harm” is not the result of the religious objector seeking to have contraceptives banned (or alcohol or Saturday work), but because the government has chosen to force third parties to distribute a product. The States thus have it backward when they suggest that women will be forced to “bear the cost of their employers’ religious views about contraceptives.” Mot. 21, 30. The Little Sisters’ beliefs about contraceptives are cost-free; the “cost” comes in because the government initially chose the Little Sisters, rather than some other delivery method, to provide such coverage. Per *Hobby Lobby*, the burdens on third parties are properly considered under the compelling interest test, not as a separate exception to RFRA. 573 U.S. at 731-32. As described above, that interest is not compelling here.

1 c. After *Zubik*, courts have unanimously found the Mandate as applied to religious
 2 employers violated RFRA.

3 Since the Supreme Court's *Zubik* order, every single religious employer case that has been litigated
 4 to conclusion has resulted in a permanent injunction. Those injunctions all include conclusions of law
 5 under Rule 65 that a RFRA violation and forbid the agencies from enforcing the mandate. For
 6 example:

- 7 • *Wheaton Coll. v. Azar*, No. 1:13-cv-8910 (N.D. Ill. Feb. 22, 2018), Dkt. 119 at 3
 8 ("enforcement of the contraceptive mandate against Wheaton would violate Wheaton's
 9 rights under" RFRA);
- 10 • *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt. 82 at
 11 1-2 ("enforcement of the mandate against Plaintiffs, either through the accommodation or
 12 other regulatory means . . . violated and would violate the Religious Freedom Restoration
 13 Act");
- 14 • *Reaching Souls Int'l, Inc. v. Azar*, No. 13-cv-01092 (W.D. Okla. Mar. 15, 2018), Dkt. 95
 15 at 3-4 ("enforcement of the contraceptive mandate against Plaintiffs . . . violated and would
 16 violate RFRA").

17 These post-*Zubik* injunctions join dozens of pre-*Zubik* injunctions in which federal judges found,
 18 over HHS's objection, that the prior system violates RFRA. All told, more than 50 RFRA-based
 19 injunctions continue to bind the federal agencies. *See supra* notes 4 & 5.

20 d. Where courts are divided, government has discretion to err on the side of not violating
 21 civil rights.

22 Since federal agencies have to implement national policy for all 50 states, it was at least a
 23 reasonable act of discretion for the agencies to comply with multiple injunctions and err on the side of
 24 not burdening religious liberty. RFRA is more than a judicial remedy; it "applies to all Federal law."
 25 42 U.S.C. § 2000bb-3. *See also* 42 U.S.C. § 2000bb-2(1) ("the term 'government' includes a[n]
 26 agency . . . of the United States."). When agencies implement federal law, they are necessarily
 27 implementing RFRA, and they are duty-bound to obey it. Accordingly, the Office of Legal Counsel
 28 has advised agencies that they can accommodate persons who they have reason to believe will face a

1 substantial burden on religious exercise. *See, e.g., Application of the Religious Freedom Restoration*
 2 *Act to the Award of a Grant Pursuant to the Juvenile Justice and Delinquency Prevention Act*, 31 Op.
 3 O.L.C. 162, 176-77 (2007); *cf. Charitable Choice Regulations Applicable to States Receiving*
 4 *Substance Abuse Prevention and Treatment Block Grants*, 68 Fed. Reg. 56,430, 56,435 (Sept. 30,
 5 2003).

6 So too, here, the agencies were correct to the extent they erred on the side of protecting religious
 7 exercise under RFRA. This is particularly true because more than 50 federal courts have entered
 8 RFRA-based injunctions. That is why Congress made the Establishment Clause—not judicial
 9 pronouncements on the substantial burden test—the outer limit on exemptions: “Granting . . .
 10 exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation
 11 of this chapter.” 42 U.S.C. § 2000bb-4. RFRA thereby expresses Congress’s intent that federal
 12 agencies be allowed some leeway when accommodating religious exercise. Thus, the Final Rule is
 13 well within the discretion committed to HHS under the ACA and RFRA.

14 *4. Section 1554 of the ACA does not prohibit the Final Rule.*

15 Congress itself (a) chose not to mandate contraceptive coverage at all but left the matter entirely
 16 to HRSA’s discretion, and (b) chose to allow grandfathered plans serving tens of millions of women
 17 to not cover preventive services. In light of these choices, it makes no sense to suggest that the ACA
 18 treats failure to extend a mandate to each and every potential employer as “creat[ing] an[]”
 19 “unreasonable barrier[]” or “imped[ing] timely access to health care.” 42 U.S.C. § 18114. *See Mot.* 35-
 20 36. Furthermore, in light of (a) the existing injunctions, (b) the wide availability of contraceptives
 21 generally, and (c) Title X programs available to provide contraceptives, the Final Rule does not create
 22 an unreasonable barrier or impede timely access.

5. Section 1557 of the ACA does not prohibit the Final Rule.

The States claim that the Final Rule violates section 1557 of the ACA, Mot. 36-37, which prohibits discrimination “on the ground prohibited under . . . title IX of the Education Amendments of 1972.” 42 U.S.C. § 18116(a). But Title IX does not apply to organizations “controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization.” 20 U.S.C. § 1681(a)(3). Therefore, an exemption which protects religious organizations cannot be inconsistent with Section 1557, since Section 1557 itself incorporates the broad religious exemption scheme of Title IX. *See Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016) (noting both religious and abortion-related exemptions).

By the States' reasoning, every change to the women's preventive services mandate violates Section 1557, and the very Mandate itself—which treats women different from men—violates Section 1557. Such an absurd result cannot have been Congress's intent; and if the Court finds otherwise, the entire Mandate must be struck down.

B. The Final Rule is not arbitrary and capricious.

Arbitrary and capricious review requires that “an agency ‘examine the relevant data and articulate a satisfactory explanation for its action.’” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *see id.* at 515 (agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are *better* than the reasons for the old one”).

The agencies' rule change was fully justified by a factual finding and a logical conclusion, both of which were reasonable and explained. First, the agencies found they were mistaken to conclude previously that the "accommodation" regulatory mechanism functioned as an opt-out for religious

1 employers. Second, the Mandate—regulatory mechanism or not—burdened religious employers, and
 2 those burdens could not be justified without clear evidence that the burdens served the intended interest.

3 ***The “accommodation” as an Opt-Out.*** The agencies had previously described the accommodation
 4 in litigation as simply “opting out” of contraceptive coverage. *See* Br. for the Resp’ts at 25, *Zubik*, 136
 5 S. Ct. 1557, <https://bit.ly/2DiCj32>. In the Final Rule, the agencies explained why that was mistaken.
 6 “In the past, the Departments had stated in our regulations and court briefs,” as in *Zubik*, “that the
 7 previous accommodation process required contraceptive coverage or payments in a way that is
 8 ‘seamless’ with the coverage provided by the objecting employer.” 83 Fed. Reg. at 57,544. Put
 9 differently, the accommodation’s actual structure continued to require employers to provide plans with
 10 objectionable coverage, even if payments were segregated—meaning it failed to “accommodate” any
 11 theological concerns about complicity not tied to a specific financing structure. “As a result, in
 12 significant respects, that previous accommodation process did not actually accommodate the
 13 objections of many entities, as many entities with religious objections have argued.” 83 Fed. Reg. at
 14 57,544.

15 ***Burden Not Justified by Compelling Interest.*** As the agencies recognized, employers being made
 16 to choose between “significant penalties” and involvement with contraceptive coverage in a manner
 17 “inconsistent with their religious observance or practice” was the precise “substantial burden identified
 18 by the Supreme Court in *Hobby Lobby*.” 83 Fed. Reg. at 57,545-46. As such, the agencies had the
 19 burden to show a compelling interest served by enforcing the Mandate against religious objectors, and
 20 that the accommodation-modified Mandate was the least restrictive means of serving the interest. And
 21 they reasonably concluded that if the link between the Mandate and contraceptive access and use was
 22 “not clear,” so too was the link between the Mandate and any compelling interest in ensuring
 23 widespread contraceptive access and use. *See* 83 Fed. Reg. at 57,556. The agencies also recognized

that any interest in denying the exception to religious objectors specifically—RFRA’s “burden to the person” inquiry, 42 U.S.C. § 2000bb-1(b)—was further reduced by the fact that “many or most women potentially affected by the expanded exemptions . . . may not be impacted by these rules at all” in light of other exceptions and a growing number of permanent injunctions that prevented the Mandate’s application. 83 Fed. Reg. at 57,550. The agencies also provided legal analysis on the substantial burden question, particularly on why an interest in “seamlessness” would likely fail the Supreme Court’s standards for a compelling interest, 83 Fed. Reg. at 57,548 (detailing damage to that interest under current law). Given the agencies’ factual conclusions that the benefits of denying religious exemptions were highly uncertain, the agencies’ final decision to grant exemptions under RFRA was far from arbitrary. Further, the States’ own declarations undercut the idea that allowing a few more employers to access a religious exemption would undercut the interests served by the Mandate, given that those declarations tout the comprehensive effectiveness of a system that has always incorporated broader exemptions. *See, e.g.*, Kost Decl. at 14, Dkt. 174-19 (“[T]he ACA’s contraceptive coverage mandate has had its intended effect of removing cost barriers to obtaining contraception.”); Custer Decl. at 6, Dkt. 174-6 (thirty-year low in pregnancies); Skinner Decl. at 11, Dkt. 174-32 (“dramatic decrease in the numbers of unintended pregnancies, teen births and abortions”).

C. The Final Rule does not violate the Establishment Clause.

18 RFRA authorizes the government to grant “exemptions, to the extent permissible under the
19 Establishment Clause.” 42 U.S.C. § 2000bb-4. The States have argued that the Final Rule violates the
20 Establishment Clause. Mot. 51-54. Yet, over six years of hard-fought litigation, not the Obama
21 Administration, nor the lower federal courts, nor any Supreme Court Justice took the view that
22 granting relief to religious organizations would violate the Establishment Clause. And with good
23 reason: the Final Rule easily passes Establishment Clause muster under any test.

1 First, under the Supreme Court’s most recent precedent, “the Establishment Clause *must* be
 2 interpreted ‘by reference to historical practices and understandings.’” *Town of Greece v. Galloway*,
 3 572 U.S. 565, 576 (2014) (quoting *County of Allegheny v. ACLU Greater Pittsburgh Chapter*, 492
 4 U.S. 573, 670 (1989)) (emphasis added). Religious accommodations “fit[] within the tradition long
 5 followed” in our nation’s history.¹⁶ *Id.* at 577. Indeed, the historical understanding of “establishments”
 6 in some cases *requires* broad exemptions for religious employers. In *Hosanna-Tabor*, a unanimous
 7 Supreme Court held that historical anti-establishment interests required that churches be exempt from
 8 employment discrimination laws with regard to their ministerial employees. 565 U.S. 171. That
 9 exemption is required because “the Establishment Clause . . . prohibits government involvement in
 10 such ecclesiastical decisions.” *Id.* at 189. Like the ministerial exception, the Final Rule belongs to a
 11 tradition of avoiding government interference with religious decision-making and the internal
 12 determinations of religious groups like the Little Sisters.

13 Even under the much-maligned *Lemon* test, the Supreme Court has long recognized that
 14 accommodation of religion is a permissible secular purpose, which does not advance or endorse
 15 religion, and which avoids, rather than creates, entanglement with religion.¹⁷ The leading case is
 16 *Corporation of Presiding Bishop v. Amos*. There, a federal employment law prohibited discrimination
 17 on the basis of religion. But it also included a religious exemption, which permitted religious

19 ¹⁶ See, e.g., Michael W. McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 Harv. L. Rev. 1409 (1990); Mark L. Rienzi, *The Constitutional Right Not to Kill*, 62 Emory L.J. 121 (2012) (collecting historical examples).

21 ¹⁷ The *Lemon* test is one of the most criticized tests in constitutional law. See, e.g., *Utah Highway Patrol Ass’n v. Am. Atheists, Inc.*, 565 U.S. 994 (2011) (Thomas, J., dissenting from denial of certiorari) (collecting criticism by Chief Justice Roberts and Justices Kennedy, Alito, Thomas, and Scalia); *Green v. Haskell Cty. Bd. of Comm’rs*, 574 F.3d 1235, 1245 (10th Cir. 2009) (Gorsuch, J., dissenting from denial of rehearing en banc) (noting that *Lemon* “leave[s] the state of the law ‘in Establishment Clause purgatory.’”) (citation omitted).

1 organizations to hire and fire on the basis of religion. 483 U.S. 327, 329 n.1 (1987). That exemption
 2 was challenged as a violation of the Establishment Clause, allegedly because it advanced religion by
 3 “singl[ing] out religious entities for a benefit.” *Id.* at 338. But the Supreme Court *unanimously* upheld
 4 the religious exemption, concluding that the “government acts with [a] proper purpose” when it “lift[s]
 5 a regulation that burdens the exercise of religion.” *Id.*

6 The States insist this case is more serious than *Amos*, even though *Amos* involved a far more serious
 7 burden on third parties: the loss of a job, not merely the inability to obtain one particular insurance
 8 benefit through one’s employer. The States rely instead on the earlier case of *Thornton v. Caldor*, 472
 9 U.S. 703 (1985). But the Supreme Court in *Amos* explained that the employment accommodations
 10 upheld there were distinct from the law in *Thornton*: “Undoubtedly, Mayson’s freedom of choice in
 11 religious matters was impinged upon, but it was the Church . . . and not the Government, who put him
 12 to the choice of changing his religious practices or losing his job.” *Amos*, 483 U.S. at 337 n. 15. Here,
 13 no one is being put to the choice of changing their practices or losing their job; women who do not
 14 obtain contraceptives through their employer can obtain them from a variety of different sources. Any
 15 burden on third parties is far less than that in *Thornton*. As the States’ own evidence makes exceedingly
 16 clear, employees have a variety of different means to obtain contraceptives, and the employer
 17 exemption here does not coerce an employee any more than a grandfathering exemption or small
 18 business exemption. It would upset the Religion Clauses to hold that it is perfectly acceptable for the
 19 government to exempt millions of employers through grandfathering, exempt small businesses from
 20 providing any insurance coverage at all, or exempt its own government-run plans from the preventive
 21 services mandate, but it suddenly creates an Establishment Clause violation if the government exempts
 22 the Little Sisters of the Poor too.

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1 The States' reliance upon the three-Justice plurality in *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1
 2 (1989), fares no better. First, the narrowest ground of decision among the split opinions in that case
 3 was that "content" discrimination in regulations governing press "is plainly forbidden by the Press
 4 Clause," so *Texas Monthly* arguably does not apply beyond the press context. 489 U.S. at 25-26
 5 (White, J., concurring in the judgment). But even the three-Justice plurality—which emphasized that
 6 the exemption at issue "targeted [] writings that *promulgate* the teachings of religious faith"—found
 7 that exemptions were appropriate to "remov[e] a significant state-imposed deterrent to the free
 8 exercise of religion." 489 U.S. at 15. The plurality also noted that the tax exemption would have
 9 survived if "the benefits derived by religious organizations flowed to a large number of nonreligious
 10 groups as well," or if "similar tax breaks" were available for others. 489 U.S. at 11, 14 n.4. Here, the
 11 Final Rule lifts a significant state-imposed burden on religious exercise, as dozens of courts have held.
 12 And the exemption is not unique: nonreligious employers have access to a variety of exemptions much
 13 larger than the exemption challenged here, including grandfathering, the small business exemption,
 14 and the moral objector exemption. Given the burdens on religious exercise and the variety of
 15 exemptions available—some of which pose far greater hurdles to employees than the Final Rule—the
 16 *Texas Monthly* plurality actually supports the agencies.

17 The agencies are not "advanc[ing] religion through [their] own activities and influence." *Amos*,
 18 483 U.S. at 337. They are merely lifting a severe governmental burden on private religious exercise,
 19 a burden that 50 federal courts have seen fit to lift for religious plaintiffs. Such religious
 20 accommodations are not just permissible under the Establishment Clause, they "follow[] the best of
 21 our traditions." *Zorach v. Clauson*, 343 U.S. 306, 314 (1952).

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1 **D. The Final Rule does not violate the Equal Protection Clause.**

2 The States' equal protection argument also fails. The IFRs make no sex classification. It is the
3 underlying mandate, which the States wish to *enforce*, that creates differential rights based on sex. The
4 Little Sisters and other religious groups cannot participate in (for example) the sterilization of either
5 men or women. But they only need a religious exemption from the latter because that is all the States
6 are seeking to force them to provide.

7 The Final Rule focuses on one portion of the women's preventive services mandate because that
8 is the portion that was enjoined repeatedly in court. If the agencies were creating a sex-based
9 classification when they created the Final Rule, then the courts were doing so as well when they created
10 judicial exemptions from one portion of the preventive services mandate. The same would be true of
11 the Supreme Court's ruling in *Hobby Lobby*. The States cite no case for the novel proposition that an
12 exception to a rule with a sex-based classification is itself a sex-based classification—particularly
13 where the exemption is not handed out on the basis of sex. Nor have they offered any case for the even
14 more preposterous notion that the proper judicial remedy in such a case would be to *enforce* the
15 original sex-based classification, invalidating only the exemption thereto.

16 In any case, even if the religious objector rules were subject to heightened scrutiny, they would
17 easily pass. As discussed above, a change to the rules serves a significant government interest in
18 protecting religious exercise. The Ninth Circuit has held that "it is always in the public interest to
19 prevent the violation of a party's constitutional rights," and that deprivation of constitutional rights
20 constitutes irreparable harm. *See, e.g., Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012).
21 Protecting the First Amendment and similar statutory rights of religious groups like the Little Sisters
22 is unquestionably a significant government interest. The rules are also substantially related to that
23 interest; they are based upon the known religious objectors and information gathered during the

1 rulemaking process regarding the types of employers who might seek an exemption. *See* 83 Fed. Reg.
 2 at 57,576-78. The Final Rule does not exempt “*all* employers,” but only the subset with sincere
 3 religious objections. Mot. 56. The States object that the exemption is no longer limited to churches,
 4 but as explained at length in the Rule, the exemption for churches was too narrow and posed
 5 constitutional and statutory problems. 83 Fed. Reg. at 57,544. The Final Rule is substantially related
 6 to a significant government interest.

7 **III. The States cannot prevail on their claims that the Final Rule is procedurally invalid.**

8 **A. Any procedural deficiency was cured by notice and comment before the Final Rule was
 issued.**

9 It cannot be reasonably disputed that the States had notice and an opportunity to be heard on all
 10 relevant aspects of the Final Rule prior to promulgation of the Final Rule. 5 U.S.C. § 553; *see Paulsen*
 11 *v. Daniels*, 413 F.3d 999, 1007 (9th Cir. 2005) (“interested parties” must be given notice that
 12 “enable[s] them to participate in the rulemaking process before the relevant agency adopt[s] the rule”).
 13 The Eastern District of Pennsylvania acknowledged these requirements were met. *See Pennsylvania*
 14 *v. Trump*, 351 F. Supp. 3d 791, 812 (E.D. Pa. 2019) (“[T]he States are unlikely to succeed on the
 15 merits of their argument that, in promulgating the Final Rules, the Agencies’ actions failed to meet the
 16 requirements of notice-and-comment rulemaking.”). Yet the States advance the novel theory that an
 17 otherwise compliant notice and comment period is an irrelevant nullity whenever it follows an
 18 allegedly procedurally defective interim rule. Such a rule would run counter to both Ninth Circuit
 19 precedent and common sense, and would call into question both common APA practice and the
 20 Mandate more broadly.

21 In *Paulsen*, for example, the Ninth Circuit invalidated an interim rule it found to have not complied
 22 with notice-and-comment procedures, but held the final rule “which adopted the [IFR] without change”
 23 was the effective rule, not the rule previously in force which was itself legally infirm. 413 F.3d at 1008.

This case is instructive in two ways: (1) it does not say in any way that a procedural error in an IFR taints the procedure for issuing a subsequent final rule; and (2) it specifically placed a new final rule in force where—as here—the rule previously in force was illegal. *See supra* Part II.A.3 (regulations forming contraceptive mandate violated RFRA absent exception). Likewise, in *Buschmann v. Schweiker*, the Ninth Circuit held invalid an interim final rule that failed to comply with notice and comment procedures, but declined to strike the final rule “identical to the interim regulation challenged” which all parties agreed was “valid.” 676 F.2d 352, 358 (9th Cir. 1982). The government was denied the benefit of its improperly promulgated rule, with no impact on the properly issued rule.

This comports with common sense. According to the GAO, 35% of all major rules were finalized without a prior notice of proposed rulemaking, with agencies commonly requesting post-promulgation comments. *See* U.S. Gov’t Accountability Office, GAO-13-21, *Federal Rulemaking: Agencies Could Take Additional Steps to Respond to Public Comments*, 3 n.6, 8, 24 (Dec. 2012), <http://www.gao.gov/assets/660/651052.pdf>. Adopting the States’ rule would render common post-promulgation notice-and-comment procedures as simple time wasting; if a court found good cause lacking for the interim rule to be promulgated after notice and comment, a later final rule with responses to the post-promulgation comments would be invalidated no matter how comprehensive. Further, even if a Final Rule could be struck simply because its notice-and-comment process was preceded by an IFR rather than a notice of proposed rulemaking, it would be particularly odd to follow that rule when the IFR was (and remains) enjoined for nearly a full year prior to the Final Rule’s promulgation. *Pennsylvania*, 351 F. Supp. 3d at 830 (IFR was enjoined in December 2017 “without any specific geographic or temporal limitation”).

It is not clear that the States mean what they say in offering this Court a *per se* rule that past procedural error taints subsequent notice and comment. After all, the States’ relief in this case—if any

1 could be had—would have to come from specifically bringing the regulations underlying the Mandate
 2 back into force as to religious objectors. And those relevant regulations—imposing a mandate, creating
 3 a religious exemption, and modifying that exemption—were themselves all initially imposed by IFR
 4 without notice and comment. Even if this Court determines it can fashion an equitable remedy without
 5 considering the validity of the prior regulations, the States’ inability to obtain relief without embracing
 6 regulations not in compliance with their legal theory just underscores how sweeping their *per se* rule
 7 is.

8 While the Eastern District of Pennsylvania came to a different conclusion, it relied on Third Circuit
 9 precedent that not only arguably conflicts with *Paulsen*, but also struck final rules under unique
 10 circumstances not applicable here. Most relevantly, the court there relied on *Natural Resources*
 11 *Defense Council, Inc. (NRDC) v. EPA*, 683 F.2d 752 (3d Cir. 1982), where the Third Circuit—in a
 12 challenge to an interim rule—also struck the final rule as part of the remedy. *See Pennsylvania*, 351
 13 F. Supp. 3d at 813 (reasoning from *NRDC* as “most directly on point”). But there, the final rule was
 14 contingent on the interim rule’s existence, as the question it asked—whether to “further suspend” an
 15 effective date—was contingent on the validity of the IFR. 683 F.2d at 757 (citation omitted); *see id.*
 16 at 768 (“Commendably, EPA did conduct a rulemaking on the question of whether its already
 17 accomplished postponement should be continued; however, that rulemaking cannot replace one on the
 18 question of whether the amendments should be postponed in the first place.”). And in any event, *NRDC*
 19 dealt with the effective repeal of a regulation passed by comprehensive notice-and-comment—not a
 20 regulation itself built on IFRs. *Id.* at 754. To the extent Ninth Circuit precedent allows for
 21 consideration of *NRDC*, it is inapposite.

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1 **B. In any event, any procedural error was harmless.**

2 The Final Rule’s detailed level of engagement and response with comments also demonstrates the
 3 States’ inability to show harm from any procedural error in the Final Rule’s notice-and-comment
 4 process where the only plausible “error” is the prior issuance of an interim final rule. “[T]he burden
 5 of showing that an [agency] error is harmful normally falls upon the party attacking” the agency action.
 6 *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009). The alleged procedural error is harmless if “the
 7 outcome of the administrative proceedings will be the same absent [the agency]’s error.” *Green Island*
 8 *Power Auth. v. FERC*, 577 F.3d 148, 165 (2d Cir. 2009); *see also PDK Labs. Inc. v. U.S. Drug Enf’t*
 9 *Admin.*, 362 F.3d 786, 799 (D.C. Cir. 2004) (“If the agency’s mistake did not affect the outcome, if it
 10 did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.”).

11 While “harmless error analysis in administrative rulemaking” includes “the process as well as the
 12 result,” this means simply that “the purposes” of notice must be “fully satisfied” and that “a full and
 13 fair opportunity to be heard” took place. *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th
 14 Cir. 1992) (citations omitted). Here, as explained above, the agencies filed detailed responses to public
 15 comments, revisiting and revising the prior IFR in substance, style, and analysis. The States have not
 16 persuasively explained why, under the circumstances, the opportunity to be heard with regard to the
 17 Final Rule would have been qualitatively different had the IFR come in the form of a detailed Notice
 18 of Proposed Rulemaking that was substantively unaltered after comments. That is particularly true
 19 where, as here, the agencies have publicly stated their understanding that continuation of the prior
 20 rules violates a federal civil rights law.

21 The Little Sisters also preserve their argument, pending further review, that “immediately
 22 remedying the RFRA violation constituted good cause” for the prior IFR. *See California*, 911 F.3d at
 23 577 (finding change of position “nine months” following prior administration’s contrary statements

1 was insufficiently explained). The Little Sisters continue to believe both that the IFR promulgating a
 2 religious exception was sufficiently explained, and that regardless, any procedural violation was
 3 harmless given the actual existence of a RFRA violation. *See United States v. Reynolds*, 710 F.3d 498,
 4 517-18 (3d Cir. 2013) (while “harmless error analysis” considers “the process as well as the result,”
 5 even “the complete failure to provide for notice and comments is harmless” when “the conclusion
 6 reached in the administrative rule was the only possible conclusion” (citations omitted)).

7 CONCLUSION

8 This Court should dismiss the States’ complaint. In the alternative, it should grant summary
 9 judgment in favor of the Defendants and deny the States’ summary judgment motion.

10 Dated: May 31, 2019

Respectfully submitted,

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